Form Approved
OMB No. 0920-0840

Expiration Date 02/29/2016

"Informing the Development of Mobile Apps for HIV Prevention, Treatment, & Care"

Attachment 3e. Consent form for Usability Design Sessions

Columbia University Medical Center Consent Form

Medical Center Institutional Review Board: 212-305-5883

Consent Form #: CF-AAAL6602 Copied From: CF-AAAL2735

Attached to Protocol: IRB-AAAK3559

Principal Investigator: Rebecca Schnall (rb897)

IRB Protocol Title: Informing the Development of Mobile Apps for HIV Prevention,

Treatment and Care

Consent Number: CF-AAAL6602

Participation Duration: 1.5 hours

Anticipated Number of Subjects: 20

Consent -Usability -Informing the Development of a Mobile App for HIV Prevention, care and treatment (Reading Flesch-Kincaid Grade Level 7.7)

Contact_____

Contact	Title	Contact Type	Numbers
Rebecca Schnall	Assistant Professor of Nursing	Principal Investigator	Telephone: 212-342-6886

Research Purpose

This is a research study to assess the usability of a mobile app for HIV prevention and care. We will use feedback from participants to refine the current mobile app design.

Information on Research_____

INTRODUCTION

You are being asked to participate in this research study, which is funded by the Centers for Disease Control and Prevention (CDC), because you are living with HIV or are at high-risk for HIV.

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:

- Why the study is being done;
- The things that you will be asked to do if you are in the study;
- Any known risks involved;
- Any potential benefit; and
- Options, other than taking part in this study, that you have.

A member of the research team for this project will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

The purpose of this research is described below in the 'What is Involved in This Study?' section of this consent form.

This consent form is written to address a research subject.

WHAT IS INVOLVED IN THIS STUDY?

The usability testing will take place in a laboratory setting; you and the researcher will be in a room with a computer. This computer will have a recording device connected to the computer screen. You will not be video recorded; only the computer screen and your voice will be recorded.

You will begin by filling out a brief background and computer usage survey. Next, instructions about the functions of the mobile app for HIV prevention, testing and care will be provided. You will then be provided with scenarios, which are consistent with individuals who may use the mobile app. These scenarios are designed to walk you through all of the functions of the computer-based system.

During each task we will be asking you to think aloud about your expectations and reactions to the application as you work with the system. After each scenario you will be asked to provide comments about your reactions as a user of the computer-based system.

Throughout your interaction with the system we will be collecting several pieces of information. We will be recording your interaction with the system via recorder that is connected to the computer that you are using. The researcher will be at your side taking notes about the system's performance as well as measuring the start and stop times of each task. At times, we may prompt you to tell us what you are thinking. We realize that providing commentary may be distracting, but it is important for us to know what you are thinking as you carry out the tasks.

PERMISSION FOR FUTURE CONTACT

The researchers may want to contact you in the future. This study has the potential for revealing information about mobile app for HIV prevention and treatment. We would contact you only once to solicit you participation in any research associated with the current study.

Please initial below to show whether or not you give permission for future contact.

_____ (initial) I give permission to be contacted in the future for research purposes.

_____ (initial) I give permission to be contacted in the future for information relating to this study.

Risks_____

You may feel some discomfort during the research by being asked to think aloud while you are using the computer, if you are unfamiliar with some of the computer skills that are required to use the system, or if you feel self-conscious by being observed. If you are uncomfortable for any reason, you may discontinue the research session at any time.

Benefits_____

There are no personal benefits to participating in this study. Your feedback has the potential to assist us in designing a more useful and easy to use application.

Alternative Procedures_____

You have the option to not participate in this research. At any point during the session you may ask the researcher to stop the session or to delete all or part of the computer and/or voice recording.

Privacy_____

Columbia University is conducting this study. The study is funded by the Centers for Disease Control and Prevention (CDC).

Every effort will be taken to protect your identity as a participant in this study. You will not be identified in any report or publication of this study or its results. Your computer and audio recordings will be assigned a unique identification number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file.

Any information collected during this study that can identify you by name will be kept private.

We will do everything we can to keep your data secure, however, complete privacy cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

By participating in the usability study you grant permission for usability data to be made available to:

- The investigator and study staff who may be evaluating the study;
- Columbia University; and
- Applicable Institutional Review Boards ("IRBs") that independently review the study to assure adequate protection of research participants, as required by federal regulations.

Data will be transferred to CDC but will not include any information that will identify you directly.

The recordings will be destroyed after analysis is completed. If the results of the study are published or presented at a medical or scientific meeting you will not be identified.

Token of Appreciation

In appreciation for the time spent participating in the research you will receive a $25 cash voucher.

Additional Costs

There are no costs to you for participating in this study.

Voluntary Participation

Your participation in the study is voluntary. You may decide not to participate in the study. If you decide to participate, you are free to withdraw from the study at any time. Your decision to not participate or to withdraw from the study will not affect your future care or status with this investigator.

Additional Information_____

If you have any questions or concerns about the study, you may contact Rebecca Schnall RN, PhD at 212-342-6886.

If you have any questions about your rights as a subject, you may contact:

Institutional Review Board

Columbia University Medical Center

722 West 168th Street, 4th Floor

New York, NY 10032

Telephone: (212) 305-5883

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

Recording

We are asking for your permission to allow us to both audiotape your voice and videotape the computer screen as part of that research study.

The recording(s) will be used for analysis by the research team.

The recording(s) will include screen shots of the computer and your words and your face will be blocked out.

The recording(s) will be stored on a password protected computer in a locked office in the Columbia University School of Nursing and will be destroyed upon publication of the results.

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

Statement of Consent

I have read the above purpose of the study, and understand my role in taking part in the research. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later, about the research, I can ask the investigator listed above. I understand that I may refuse to participate or withdraw from participation at any time without jeopardizing my employment, student status or other rights to which I am entitled. The investigator may withdraw me at his/her professional discretion. If I have questions about my rights as a research participant, I can call the Institutional Review Board office at CUMC (212)305-5883. I certify that I am 18 years of age or older and freely give my consent to participate in this study. I will receive a copy of this document for my records.

Signature

Study Participant

Print Name_____Signature_____Date_____

Person Obtaining Consent

Print Name_____Signature_____Date_____